K123137: 510(K) SUMMARY

DEC 0 5 2012

This 510(k) Summary is provided in accordance with 21 CFR 807.92.

Date of preparation:	04 October 2012
Revised Date:	05 November 2012
Submitter information:	Varian Medical Systems 2101 Fourth Avenue, Suite 500 Seattle, WA 98121 Phone: 206-254-0600 Fax: 206-254-0606
Contact:	Marcia A Page Director Quality Assurance and Regulatory Affairs
Device trade name:	Calypso® System Calypso® System with Dynamic Edge™ Gating
Common name:	Patient localization system
Classification name:	Medical charged-particle radiation therapy system
Classification:	CFR 892.5050 Class II Product code: IYE
Predicate devices:	Calypso System (K060906, K102373, K112768)

Device Description:

The Calypso System utilizes non-ionizing electromagnetic and optical technology to provide accurate, objective, and continuous localization of a treatment target for patient alignment and target position monitoring during radiation therapy. Use of the Calypso System for target localization is based on the system's detection of non-ionizing electromagnetic signals from passive markers, called Beacon® transponders. The Beacon transponders are implanted in or near the treatment target or placed externally on the surface of a patient.

Implanted Beacon transponders when used with the Calypso System enable objective measurement of the location of the target in 3 dimensions. The system operator uses this information to align the patient's treatment target to the isocenter of the therapy system prior to treatment. This information can also be used to monitor (track) the position of the treatment target during radiation therapy treatment.

When using Surface Beacon transponders this information can be used to monitor respiratory motion and other patient motion in real time during radiotherapy. When correlated to the patient's treatment target motion the system provides objective measurement of the location of the target in 3 dimensions.

The Dynamic Edge Gating feature enables the Calypso System to connect with radiation therapy systems configured with gating capabilities via an interface to external systems. With this feature added to the Calypso System, a beam hold is signaled to the radiation therapy system when the treatment target position has moved outside the defined tracking limits. The radiation therapy system is signaled to remove the beam-hold upon the target's return to a position inside the defined tracking limits.

Indications for Use:
The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

The optional Dynamic Edge™ Gating component may signal a radiation therapy system to impose a beam-hold when the treatment target position has moved outside the defined tracking limits and to signal the radiation therapy system to remove the beam-hold upon the target's return to a position inside the defined tracking limits. The Dynamic Edge Gating feature has been shown to be compatible with Varian and Siemens radiation therapy treatment systems with external gating interfaces.

Implanted Beacon® transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon transponders are indicated for implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed) to align and monitor the treatment isocenter in real time during radiation therapy.

Surface Beacon® transponders are indicated for temporary external placement on the skin, to monitor respiratory motion and other patient motion in real time during radiation therapy.

Technological Characteristics – See device comparison table below

Feature and/or Specification of the Calypso System	**Cleared Calypso System Feature/Specification**	**Modified Calypso System Feature/ Specification**
Infrared optical system	Cameras and infrared targets on array and Beacon Transponders	No change
Monitoring	Real Time Monitor patient motion	No change
Tracking	Real Time Tracking Patient and Respiratory motion	No change
Gating	Interface to external systems	No change
Records	Display and Record motion	No change
Computer hardware and software	Computer systems (console and tracking station) to control device functions and provide for user interface	No change
Electromagnetic technology (array)	Used to track motion during therapeutic procedures	No change
Compatibility with the environment and other devices	Operates in a radiation therapy system environment	No change
Electrical safety mechanical safety	EN60601-1: 1990 / A1:1993 / A2:1995 EN 60601-1-1: 2001	EN60601-1 EN 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
EMC Safety	EN60601-1-2 ed. 2.0	No Change

Summary of Performance Testing:

Results of software, hardware and system verification and validations testing demonstrate that the Calypso System satisfies the intended use as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Marcia Page
Director Quality Assurance and Regulatory Affairs
Varian Medical Systems
2101 Fourth Avenue South, Suite 500
SEATTLE, WA 98121

December 5, 2012

Re: K123137
Trade/Device Name: Calypso® System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 4, 2012
Received: October 5, 2012

Dear Ms. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123137

Device Name: Calypso® System

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____